



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

9 OCT 10 2000 OCT 25 P2:22

Mr. Neil Blechman  
Executive Vice President  
Twin Laboratories, Inc.  
150 Motor Parkway  
Hauppauge, New York 11788

Dear Mr. Blechman:

This is in response to your letter of September 26, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Twin Laboratories, Inc. is making the following claim, among others, for the product **Twinlab Soy Sensation**:

“...maintain healthy cholesterol levels.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, cure or mitigate diseases, namely hypercholesterolemia. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

978-0163

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Copies:

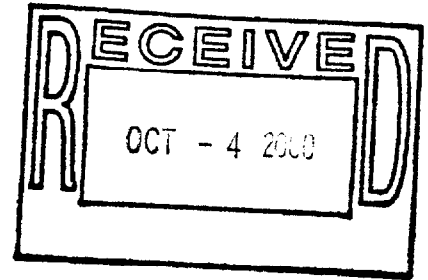
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, New York District Office, Office of Compliance, HFR-NE140

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-800 (r/f, file)  
HFS-810  
HFS-811 (file)  
HFD-310  
HFD-314 (Aronson)  
HFS-605  
HFV-228 (Benz)  
GCF-1 (Dorsey; Nickerson)  
f/t:HFS-811:rjm:10/5/00:docname:72734.adv:disc51

September 26, 2000

Office of Special Nutritionals (HFS-450)  
Center for Food Safety & Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, D.C. 20204



Dear Sir or Madam:

This letter will serve as 30-day notification, pursuant to section 403 (r)(6) of the Federal Food, Drug & Cosmetic Act and regulations promulgated thereunder.

Name and address of Dietary Supplement Manufacturer:      Twin Laboratories, Inc.  
150 Motor Parkway  
Hauppauge, NY 11788

Text of statement being made: "...to help maintain healthy cholesterol levels...to help support bone health."

Dietary supplement ingredients: Isolated Soy Proteins, Calcium, Magnesium, Potassium, Vitamin E, Zinc, Selenomethionine, Biotin, Kelp, Niacinamide, Folic Acid, Vitamin D, Vitamin A, Vitamin B-12, Pyridoxine, Riboflavin and Thiamine.

Dietary supplement brand and name: Twinlab SOY SENSATION.

As required, enclosed are two photocopies of this notification.

The signee certifies that the information contained in this notice is complete and accurate, and that Twin Laboratories, Inc., has substantiation that the statement is truthful and not misleading.

Sincerely,

A handwritten signature in cursive script that reads "Neil Blechman".

Neil Blechman  
Executive Vice President  
Twin Laboratories, Inc.

Enclosures